JUL 1 8 2001

K011756

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Ihr Zeichen yr. ref.	Ihre Nachricht vom dtd.	Unser Zeichen our ref.	Datum date

510(k) SUMMARY

ADMIRA FLOW®
(76 EBF)

1. Submitter's Name
2. Contact Person For VOCO GmbH
3. Date that 510(k) Summary Was Prepared
4. Name of the Medical Device (Classification / Common / Proprietary)
5. Legally Marketed Devices To Which Substantial Equivalence Is Claimed
6. Description of the Device
7. Intended Use of the Device
8. Technological Comparison Between Subject and Predicate Devices
9. Summary of Preclinical Performance Studies and Conclusions From Preclinical Performance Studies

1. SUBMITTER'S NAME
VOCO GmbH Anton-Flettner-Str. 1-3 27472 Cuxhaven GERMANY
Tel: 011-49-47 21 719 0 Fax: 011-49 47 21 719 140

Geschäftsführer: Manfred Plaumann, Manfred Thomas Plaumann · Amtsgericht Cuxhaven HR B 1260
Postgiro Hamburg (BLZ 200 100 20) 482 07-200 · Stadtsparkasse Cuxhaven (BLZ 241 500 01) 149 690 · Deutsche Bank Cuxhaven (BLZ 200 700 00) 85 00084

2.	*U.S. REGULATORY CONTACT PERSON FOR VOCO GmbH*
	Evan Dick, Ph.D E.G. Dick & Associates 7527 Westmoreland Avenue St. Louis, MO 63105
	Tel: (314) 721-0112 Fax: (314) 721-7591

3.	*DATE THAT510(k) SUMMARY WAS PREPARED*
	June 4, 2001

4.	*NAME OF THE MEDICAL DEVICE*	
	Classification name	*Material, tooth shade, resin (Dental 76 EBF)*
	Common / usual name	*Light-curing dental restorative material*
	Proprietary name	*ADMIRA FLOW*

5.	*LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED*
	ADMIRA (K994056, VOCO)

6. DESCRIPTION OF THE DEVICE

Admira Flow is a flowable, light-curing, and radiopaque filling material based on ormocer composite technology. Admira Flow is suitable for restorations in both anterior and posterior teeth. Admira Flow is a low viscosity composite that offers excellent wetting and adhesion. Patent-protected ormocer chemistry provides excellent strength, abrasion resistance, and adhesion to the tooth structure, while making Admira Flow easy and fast to use. Admira Flow contains 64% (by volume, 54% by weight) inorganic micro-particles (0.7 µm) and fumed silica (0.05 µm). Admira Flow cures under halogen light (blue light) and can be polished to a high gloss that is durable and color stable.

Admira Flow is available both as 1.8gm syringes and as single-use Admira Flow Caps (0.25gm) for direct intra-oral application. Admira Flow is available in six shades (A1, A2, A3, A3.5. A4, OA3.5).

7. INTENDED USE OF THE DEVICE

Admira Flow is a light-curing and radiopaque filling material. Admira Flow is intended to be used for the following types of restorations in both anterior and posterior teeth:

- fillings with minimally invasive preparation technique
- filling small cavities and sealing extended fissures
- blocking out undercuts
- lining or coating cavity walls
- Class III-V filings, including V-shaped defects and cervical caries
- repairing fillings and veneers
- luting of translucent prosthetic pieces (e.g., porcelin-only-crowns)

8. *TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES*

Admira Flow and Admira (K994056, VOCO) are both single component, light-curing restorative materials that are composed of silicate glass, methacrylate polymers and copolymers, photoinitiators, and stabilizers.

9. *SUMMARY OF PRECLINICAL PERFORMANCE STUDIES AND CONCLUSIONS FROM PRECLINICAL PERFORMANCE STUDIES*

Admira Flow is formulated from chemical components that are commonly associated with currently marketed dental composite materials.

The chemistry of Admira Flow raises no new issues or questions that effect safety, effectiveness, or biocompatibility for dental composite product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 8 2001

Voco GMBH
C/O Mr. Evan Dick
President
E.G. Dick & Associates
7527 Westmoreland Avenue
Saint Louis, Missouri 63105

Re: K011756
Trade/Device Name: Admira Flow
Regulation Number: 872.3690
Regulatory Class: II
Product Code: EBF
Dated: June 6, 2001
Received: June 6, 2001

Dear Mr. Dick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011756

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K011756

Device Name: Admira Flow

Indications For Use:

Admira Flow is a light-curing and radiopaque filling material. Admira Flow is intended to be used for the following types of restorations in both anterior and posterior teeth:

- fillings with minimally invasive preparation technique
- filling small cavities and sealing extended fissures
- blocking out undercuts
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- luting of translucent prosthetic pieces (e.g., porcelin-only-crowns)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ **OR** **Over-The-Counter** _____

(as per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011756